K011177 p.1/3

SIMS A SMITHS GROUP COMPANY

BCI

MAY 2 3 2001

Summary of Safety and Effectiveness

Submitter: Address:	SIMS BCI, Inc. N7 W22025 Johnson Road Waukesha, WI 53186
Telephone:	(262) 542-3100
Contact:	VP Regulatory Affairs
Prepared:	April 9, 2001
Proprietary Name:	BCI™ Advisor® vital signs monitor (model 9200) with new use with Life Sensing Instrument Company, Inc. HTS 820 Central Station.
Common/Classification Name:	Vital signs monitor
Predicate Devices:	BCI™ 9200 vital signs monitor (K982279) Life Sensing Instrument Company, Inc. TeleTrens Multi-parameter portable patient transmitter (K960884)

New Device Description:

The BCI 9200 vital signs monitor has been updated to include a new output function to a Life Sensing Instrument Company, Inc. HTS 820 Central Station. This new feature uses the same technology as existing legally marketed devices. This device is designed to provide full featured monitoring capabilities in a table top design. The full system features an ECG cable interface, two invasive pressure interfaces, two YSI 400/700 compatible temparature interfaces, an NIBP cuff hose connection, an SpO_2 sensor interface, an internal printer, display of patient and waveform data via a color liquid crystal display (LCD), system power status LEDs, a rotary control knob and the function keypad area consisting of five keys (on/off, IP zero, NIBP start/stop, print start/stop and alarm silence). The monitor has analog and serial output ports that are used for data communications to personal computers, printers, chart recorders, or the Life Sensing Instrument Company, Inc. HTS 820 Central Station.

Intended Use:

The 9200 vital signs monitor is intended to be used in the ICU, CCU, OR, ER, RR, Labor and Delivery rooms, special procedure labs and other areas of the hospital or clinic where low end monitoring systems are needed. The basic monitor package includes ECG (3 lead / 5 lead), impedance respiration (RSP), non-invasive blood pressure (NIBP), pulse oximetry (SpO2), two invasive blood pressures (P1 and P2), and two temperature channels (T1 and T2). A two-inch internal, graphical/alphanumeric printer and a battery are provided as options. The device permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. The device will provide fast, reliable measurements on patients ranging from children (pediatric) to adults when using the appropriate BCI accessories. The monitor may be connected to the Life Sensing Instrument Company, Inc. HTS 820 Central Station for remote monitoring of patient status.

The monitor is not intended for home use. The monitor is not intended to be an apnea monitor. It was not designed or validated for use as an apnea monitor. The monitor is not intended for neonatal use.

Performance Data:

The design of this device utilizes currently available technology found in many legally marketed devices. Both hardware and software changes were made to the device. Testing was done to ensure that BCI 9200 monitor was safe and would perform within the environments for which it is to be marketed. Testing was performed in accordance with the guidelines and standards found in the reviewer's guides for respiratory devices. Electromagnetic compatibility (EMC), electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing has been completed. The results demonstrated that the BCI 9200 monitor is in compliance with the guidelines and standards referenced in the reviewer's guides and that it performs within its specifications and functional requirements.

A full software validation test of the 9200 with new central station compatibility was completed. This test was performed while the 9200 monitor was connected to the Life Sensing Instrument, Inc. HTS 820 Central Station by a radio-frequency (RF) link. Portions of the test were also repeated with the BCI 9200 monitor and the central station connected by a hardwire. These tests showed that the device modifications operate as intended and that the changes made do not compromise the bedside performance of the monitor. Comparison of the new device's software validation test to previous software validation tests of the 9200 vital signs monitor demonstrates that the bedside performance of the monitor is not affected by the new functions. The tests were run using patient simulators with settings spanning the 9200's entire specification range for ECG, respiration, NIBP, IBP, SpO_2, and temperature. All measurements were within the specified tolerances of the monitors and simulators. These data support substantial equivalence of the bedside performance of the new 9200 monitor running to the predicate 9200 monitor.

Validation of the device performance while communicating with the Life Sensing Instrument, Inc. HTS 820 Central Station was performed. Tests were performed using both

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communications configurations (hardwire and RF) to ensure that both the BCI 9200 monitor and the central station communicate properly. Reliability of the system was confirmed by long term testing of eight BCI 9200 monitors connected to the central station using both RF and hardwire connections. These tests demonstrate that both devices provide the same information to the caregiver, whether viewing the central station or at the bedside. Testing was also performed by Life Sensing Instrument, Inc. to ensure proper functioning of their HTS 820 Central Station while working with the BCI 9200 monitor. Their tests demonstrate the performance that the central station is correctly processing the data received from the BCI 9200 monitor. These tests include alarm functions.

On the basis of these results, it is our determination that the device is safe, effective, and performs as well as the legally marketed predicate device(s).

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Respectfully,

Donald Alexander

Donald Alexander
VP Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2001

Mr. Donald J. Alexander
SIMS BCI, Inc.
N7 W22025 Johnson Road
Waukesha, WI 53186-1856

Re: K011177
BCI 9200 Vital Signs Monitor
Regulation Number: 870.2340
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: April 9, 2001
Received: April 17, 2001

Dear Mr. Alexander:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

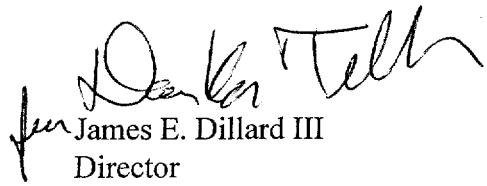
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K011177

Device Name: BCI 9200 Vital Signs Monitor with Outputs to Central Station.

Indications For Use:

Intended Use

The 9200 vital signs monitor is intended to be used in the ICU, CCU, OR, ER, RR, Labor and Delivery rooms, special procedure labs and other areas of the hospital or clinic where low end monitoring systems are needed. The basic monitor package includes ECG (3 lead / 5 lead), impedance respiration (RSP), non-invasive blood pressure (NIBP), pulse oximetry (SpO_2), two invasive blood pressures (P1 and P2), and two temperature channels (T1 and T2). A two-inch internal, graphical/alphanumeric printer and a battery are provided as options. The device permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. The device will provide fast, reliable measurements on patients ranging from children (pediatric) to adults when using the appropriate BCI accessories. The monitor may be connected to the Life Sensing Instrument Company, Inc. HTS 820 Central Station for remote monitoring of patient status.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011177

Prescription Use ✓ OR Over-The_Counter Use _____
(Per 21 CFR 801.109)